COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 14-XII-2007
C(2007)6675

NOT FOR PUBLICATION

COMMISSION DECISION

of 14-XII-2007

amending, for the purposes of its extension, the marketing authorisation granted by Decision C(2004)3160 for "Ariclaim - duloxetine hydrochloride", a medicinal product for human use

(ONLY THE DUTCH TEXT IS AUTHENTIC)

COMMISSION DECISION

of 14-XII-2007

amending, for the purposes of its extension, the marketing authorisation granted by Decision C(2004)3160 for "Ariclaim - duloxetine hydrochloride", a medicinal product for human use

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1], and in particular Article 10(2) thereof,

Having regard to the application(s) for extension within the meaning of Annex II to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93[2], submitted by Eli Lilly Nederland B.V. on 22 July 2007, under Article 4(1) of Regulation (EC) No 726/2004,

Having regard to the opinion(s) of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 18 October 2007,

Whereas:

(1) The medicinal product "Ariclaim - duloxetine hydrochloride", entered in the Community register of medicinal products under the numbers EU/1/04/283/001-007 and authorised by Commission Decision C(2004)3160 of 11 August 2004, remains in compliance with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3].

(2) The amendments requested should therefore be granted.

(3) Decision C(2004)3160 should therefore be amended accordingly,

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

---

[1] OJ L 136, 30.4.2004, p. 1, Regulation as amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p.1).

[2] OJ L 159, 27.6.2003, p. 24.

[3] OJ L 311, 28.11.2001, p. 67, Directive as last amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p.1).

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2004)3160 is amended as follows:

1) The following numbers are added to Article 1 and entered in the Community register of medicinal products:

EU/1/04/283/008	Ariclaim-30 mg-Gastro-resistant capsule, hard-Oral use-blister (PVC/PE/PCTFE/alu)-7
EU/1/04/283/009	Ariclaim-30 mg-Gastro-resistant capsule, hard-Oral use-blister (PVC/PE/PCTFE/alu)-28
EU/1/04/283/010	Ariclaim-30 mg-Gastro-resistant capsule, hard-Oral use-blister (PVC/PE/PCTFE/alu)-98
EU/1/04/283/011	Ariclaim-60 mg-Gastro-resistant capsule, hard-Oral use-blister (PVC/PE/PCTFE/alu)-28
EU/1/04/283/012	Ariclaim-60 mg-Gastro-resistant capsule, hard-Oral use-blister (PVC/PE/PCTFE/alu)-98

2) Annex I is replaced by the text set out in Annex I to this Decision;

3) Annex II is replaced by the text set out in Annex II to this Decision;

4) Annex III is replaced by the text set out in Annex III to this Decision.

Article 2

This Decision is addressed to Eli Lilly Nederland B.V., Grootslag 1-5, 3991 RA Houten, Nederland.

Done at Brussels, 14-XII-2007

For the Commission
Heinz ZOUREK
Director-General